



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 14

[Docket No. FDA-2016-N-0001]

Pharmaceutical Science and Clinical Pharmacology Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the standing advisory committees' regulations to change the name of the Advisory Committee for Pharmaceutical Science and Clinical Pharmacology. This action is being taken to reflect the change made to the charter for this advisory committee.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The name change became applicable January 22, 2016.

FOR FURTHER INFORMATION CONTACT: Teresa Hays, Committee Management Officer, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-8220.

SUPPLEMENTARY INFORMATION: FDA is announcing that the name of the Advisory Committee for Pharmaceutical Science and Clinical Pharmacology, which was established on January 22, 1990, has been changed. The Agency decided that the name "Pharmaceutical Science and Clinical Pharmacology Advisory Committee" more accurately describes the subject areas for which the committee is responsible. The committee reviews and evaluates scientific, clinical, and technical issues related to the safety and effectiveness of drug products for use in

the treatment of a broad spectrum of human diseases; the quality characteristics that such drugs purport or are represented to have and, as required, any other product for which the Food and Drug Administration has regulatory responsibility; and makes appropriate recommendations to the Commissioner of Food and Drugs. The committee may also review Agency sponsored intramural and extramural biomedical research programs in support of FDA's drug regulatory responsibilities and its critical path initiatives related to improving the efficacy and safety of drugs and improving the efficiency of drug development.

The Pharmaceutical Science and Clinical Pharmacology Advisory Committee name was changed in the charter renewal dated January 22, 2016. In this final rule, FDA is revising 21 CFR 14.100(c)(15) to reflect the change.

Publication of this final rule constitutes a final action on this change under the Administrative Procedure Act. Under 5 U.S.C. 553(b)(3)(B) and (d) and 21 CFR 10.40(d) and (e), the Agency finds good cause to dispense with notice and public procedures and to proceed to an immediately effective regulation. Such notice and procedures are unnecessary and are not in the public interest because the final rule is merely codifying the new name of the advisory committee to reflect the current committee charter.

List of Subjects in 21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs, 21 CFR part 14 is amended as follows:

PART 14--PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

1. The authority citation for 21 CFR part 14 continues to read follows:

Authority: 5 U.S.C. App. 2; 15 U.S.C. 1451-1461, 21 U.S.C. 41-50, 141-149, 321-394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264, Pub. L. 107-109; Pub. L. 108-155; Pub. L. 113-54.

2. Section 14.100 is amended by revising the heading of paragraph (c)(15) to read as follows:

§ 14.100 List of standing advisory committees.

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(c)* * *

(15) *Pharmaceutical Science and Clinical Pharmacology Advisory Committee.* * * *

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Dated: March 1, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

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